

**In the Claims**

This listing of claims will replace all prior versions, and listing, of claims in the application.

Claims 1-18 were previously canceled. Please cancel claims 19-37.

Please add new claims 38-55 that correspond to previously presented Claims 19-25 and 28-37.

38. (New): A method for enhancing the formation of a solid, non-migratory coherent mass at a selected vascular site of a mammal which method comprises:

- (a) placing a delivery device having an ejection port at a selected vascular site in a mammal;
- (b) delivering through the ejection port of the delivery device a composition capable of embolizing an aneurysm at a vascular site comprising:

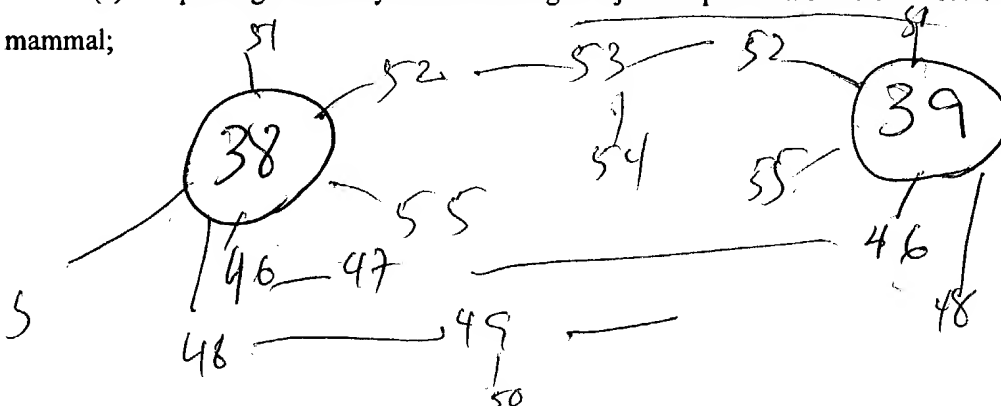
- a. a biocompatible polymer at a concentration of from about 12 to about 50 weight percent based on the total weight of the composition;
- b. a biocompatible contrast agent wherein a sufficient amount of said contrast agent is employed in said composition to effect visualization in vivo; and
- c. a biocompatible solvent which solubilizes said biocompatible polymer;

wherein sufficient amounts of said polymer are employed in said composition such that upon delivery to said vascular site a polymer precipitate forms which embolizes said vascular site;

and further wherein the biocompatible polymer has a molecular weight and/or concentration sufficient to impart to the composition a viscosity of at least about 150 cSt at 40 °C.

39. (New): A method for enhancing the formation of a solid, non-migratory coherent mass at a selected vascular site of a mammal which method comprises:

- (a) placing a delivery device having an ejection port at a selected vascular site in a mammal;



(b) delivering through the ejection port of the delivery device a composition capable of embolizing an aneurysm at a vascular site comprising:

- a) a biocompatible polymer at a concentration of from about 12 to about 50 weight percent;
- b) a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent; and
- c) a biocompatible solvent from about 10 to 88 weight percent;

wherein the weight percents of the biocompatible polymer, contrast agent, and biocompatible solvent are based on the total weight of the composition;

and further wherein the biocompatible polymer has a molecular weight and/or concentration sufficient to impart to the composition a viscosity of at least about 150 cSt at 40 °C.

40. (New): The method according to Claim 38 or Claim 39 wherein, prior to (b) above, a blood flow attenuation device is inserted immediately upstream the ejection port of said catheter.

41. (New): The method according to Claim 40 wherein, said blood flow attenuation device is an inflatable microballoon which permits both normal and attenuated blood flow depending upon whether the microballoon is deflated or inflated.

42. (New): The method according to Claim 38 or Claim 39 wherein said composition has a viscosity of at least about 200 cSt at 40 °C.

43. (New): The method according to Claim 42 wherein said composition has a viscosity of at least about 500 cSt at 40 °C.

44. (New): The method according to Claim 43 wherein said composition has a viscosity of from about 500 to 5,000 cSt at 40 °C.

45. (New): The method according to Claim 38 or Claim 39 wherein said composition has a migration distance from the point of injection of less than 25 mm.

46. (New): The method according to Claim 38 or Claim 39 wherein said biocompatible solvent is selected from the group consisting of ethyl lactate, dimethylsulfoxide, ethanol and acetone.

47. (New): The method according to Claim 46 wherein said biocompatible solvent is dimethylsulfoxide.

48. (New): The method according to Claim 38 or Claim 39 wherein said contrast agent is a water insoluble contrast agent.

49. (New): The method according to Claim 48 wherein said water insoluble contrast agent is selected from the group consisting of tantalum, tantalum oxide, tungsten and barium sulfate.

50. (New): The method according to Claim 49 wherein said contrast agent is tantalum.

51. (New): The method according to Claim 38 or Claim 39 wherein said contrast agent is a water soluble contrast agent.

52. (New): The method according to Claim 38 or Claim 39 wherein said biocompatible polymer is a non-biodegradable, biocompatible polymer.

53. (New): The method according to Claim 52 wherein said non-biodegradable, biocompatible polymer is selected from the group consisting of cellulose acetates, ethylene vinyl alcohol copolymers, hydrogels, polyacrylonitrile, polyvinylacetate, cellulose acetate butyrate, nitrocellulose, copolymers of urethane/carbonate, copolymers of styrene/maleic acid, and mixtures thereof.

54. (New): The method according to Claim 53 wherein said biocompatible polymer is an ethylene and vinyl alcohol copolymer.

55. (New): The method according to Claim 38 or Claim 39 wherein said biocompatible polymer is a biodegradable, biocompatible polymer.

Now presented Claim 39 corresponds to previously presented Claims 2 and 19 with similar concentration recitations as found in the specification at the specification at page 5, lines 5-6 and 15-16; page 6, lines 19-20; and page 11, lines 17-21.

Claims 40-55 correspond to previously presented Claims 20-25 and 28-37 respectively.

No new matter has been added.

Entry of these amendments is requested.

Rejection Under 35 U.S.C. §112, second paragraph

Claims 1-18 stand rejected under 35 U.S.C. §112, second paragraph, for the reasons noted of record in the Office Action. Applicants note that this rejection is moot in view of the fact that Claims 1-18 are not pending in this application.

As to now presented Claims 38-55, these claims recite "wherein the biocompatible polymer has a molecular weight and/or concentration sufficient to impart to the composition a viscosity of at least about 150 cSt at 40°C." Applicants maintain that these amendments render moot any application of this rejection against now presented Claims 38-55. However, in order to expedite prosecution, Applicants offer the following:

The viscosity recited in the claims by necessity refers to the composition comprising the polymer, the biocompatible solvent, and the contrast agent, as opposed to the precipitate formed therefrom. Specifically, the language of the rejected claims recites a composition comprising a biocompatible polymer, a biocompatible contrast agent, and a biocompatible solvent which "solubilizes said biocompatible polymer". The claims later recite that this composition has the recited viscosity.

Contrarily, as is well known in the art (see, e.g., U.S. Patent No. 5,695,480), precipitation occurs when sufficient biocompatible solvent dissipates into the blood or other body fluid such that the polymer no longer is soluble in the resulting fluid environment. In such a case, the composition claim discussed above no longer applies since the biocompatible solvent no longer solubilizes the polymer.

Withdrawal of this rejection is requested.

Claim 2 stands rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite for failing to specify what the phrase "complete composition" refers to. As above, Claim 2 is not presented in this application and, accordingly, this rejection is moot.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution in the instant application, now presented Claim 38 does not employ the term "complete." Applicants maintain that this amendment does not limit the scope afforded by Claim 2 as one of ordinary skill in the art would recognize that "the complete composition" and "the composition" refer to the same entity. In light of the foregoing, withdrawal of this rejection is requested.

### Rejections Under 35 U.S.C. §102/§103(a)

Claims 1-13 and 15-37 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by, or in the alternative, allegedly obvious under 35 U.S.C. § 103(a) by U.S. Patent No. 5,695,480 to Evans et al. ("Evans"). According to the Examiner, because the rejected claims are directed to compositions comprising a biocompatible polymer such as ethylene vinyl alcohol copolymer, a biocompatible contrast agent such as tantalum, and a biocompatible solvent such as dimethyl sulfoxide (DMSO), and because "Evans discloses compositions comprising ethylene vinyl alcohol copolymer in concentrations of 8 % weight, tantalum in concentrations of 30 % weight and DMSO in amounts of 100 ml (52-87.5 % weight) ... [and having a viscosity of] less than 60 centipoise at 20°C, " the rejected claims are anticipated. *Office Action, Pages 5-6.*<sup>1</sup> According to the Examiner, "[a]lthough Evans does not specifically recite the instantly claimed viscosity of 150 cSt at 40°C or migration distance, ... [the] compositions disclosed by Evans inherently possess the same viscosity and migration distance as the instantly claimed invention, because Evans' compositions comprise similar component[s] used in overlapping range[s] of concentrations as those claimed in the instant

<sup>1</sup> Applicants respectfully wish to set forth the percentages contained in the Evans publication. Example 1 of the Evans publication references a first and a second composition. Both compositions contain 8 gm EVOH, 30 gm tantalum and 100 mL DMSO. The weight of the total composition is 8 gm+ 30 gm+ (100 mL x 1.1 gm/mL) = 148 gm. Therefore, the weight percent, based on the total composition, of EVOH is about  $(8/148) = 5.4\%$ ; of tantalum is about  $(30/148) = 20.3\%$ ; and of DMSO is about  $(110/148) = 74.3\%$ . See Evans, Column 10, Lines 15-47. The compositions claimed in Evans include from about 2.5 to about 8.0 weight percent of a biocompatible polymer, from about 10 to about 40 weight percent of a water insoluble, biocompatible contrast agent, and from about 52 to about 87.5 weight percent of a biocompatible solvent. See Evans, Column 11, Claim 1. Similar to Evans, the weight percents listed for components in the compositions claimed in this application are listed based upon the total weight of the composition.